



## NATIONAL TOXICOLOGY PROGRAM

Department of Health and Human Services

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October 30, 2007

**To:** NTP Board of Scientific Counselors

**From:** Director, Center for the Evaluation of Risks to Human Reproduction (CERHR)

**Subject:** New Candidate Substances for CERHR Evaluation

The following material is provided as background for the December 6, 2007 NTP Board of Scientific Counselors (BSC) meeting and concerns proposed evaluations by CERHR. The BSC is asked to review the candidate substances under consideration with respect to the attached charge.

The NTP has a formal multi-step process for reviewing new nominations before substances are selected for CERHR evaluation. The first external step in this process is a review by the multi-agency CERHR Core Committee. The Core Committee considers each nominated substance to determine whether the available scientific information justifies its formal evaluation. The Core Committee bases its recommendations for evaluation on a substance's production volume, potential human exposure, amount of available scientific information about a substance's reproductive and developmental toxicity, and degree of public concern. In July 2007, the CERHR Core Committee recommended two nominated substances for evaluation: low-level lead (< 40 µg/dL blood) and cadmium. Public comments on the proposed evaluations were requested in the Federal Register on October 17, 2007, and through the NTP's newsletter and website.

This is the first time the BSC is being asked to provide input on whether there is sufficient concern and scientific data to warrant CERHR conducting an evaluation for a particular nominated substance. This change is consistent with the BSC role in providing input on other NTP programmatic efforts, such as providing guidance on NTP testing nominations. Once we receive your input, the NTP will carefully consider it along with other information to make a final decision on the proposed evaluations. A nominated substance might not be recommended for evaluation by the Core Committee for several reasons including (1) insufficient scientific information to determine whether the substance is or is not a reproductive or developmental toxicant, (2) existence of a recent evaluation of reproductive and development risks conducted by another agency or organization, (3) absent or limited information on human exposures, or (4) insufficient public health concern.

A description of the CERHR review process, public comments, and dossiers supporting the low-level lead and cadmium nominations are provided in the attached notebook, and are also available electronically on the NTP web site at <http://ntp.niehs.nih.gov/go/165>.

Please contact me by telephone at (919) 541-3455 or by email at [shelby@niehs.nih.gov](mailto:shelby@niehs.nih.gov) prior to the December 6 meeting if you have questions or comments regarding any of the nominations or background material.

Michael Shelby, Ph.D.

Enclosures

**Charge to the NTP Board of Scientific Counselors (BSC) for Review of Nominations  
Proposed for Evaluation by the Center for Evaluation of Risks to Human Reproduction  
(CERHR)**

Nominations proposed for evaluation by CERHR are being presented to the BSC for review and comment. The CERHR Core Committee reviewed the dossiers for these nominations and recommended them for evaluation. Following the Core Committee review, public comments were solicited on the proposed evaluations. The public BSC meeting provides an additional opportunity for program staff and the BSC to receive public comment on the proposed evaluations. The NTP asks the BSC to:

- provide its general views on the merit of the proposed evaluations.
- offer its perspective on any public comments received on these proposed evaluations.

*Specific charge questions:*

1. Does the proposed evaluation address an important issue of public health concern and/or advance the field of environmental health sciences?
2. Is the published scientific information about the substance's reproductive and developmental toxicities sufficient to support a formal evaluation? Please also consider the available information on production volume and extent of human exposure.
3. Does the substance merit CERHR evaluation and, if so, what priority (low, moderate, or high) should it be given?

If you support a CERHR evaluation of this substance:

4. Are you aware of other data or ongoing studies not in the dossier that would be relevant to a CERHR evaluation?
5. Are there specific exposure situations or susceptible subpopulations that should be given special consideration in a CERHR evaluation?
6. Are there specific developmental or reproductive endpoints that should be given special consideration in CERHR evaluation?

The BSC is asked to make a recommendation on whether CERHR should conduct the proposed evaluation.

## **CERHR NOMINATIONS PROPOSED FOR EVALUATION**

### **BACKGROUND MATERIALS [LIST]**

- CERHR review process
- Dossiers
- Public comments received

### **DISCUSSANTS**

<b>Nomination</b>	<b>BSC Discussant</b>	<b>Ad hoc Discussant</b>
Low Level Lead	Dr. Vernon Walker	Dr. Tomas Guilarte (Johns Hopkins U)
Cadmium	Dr. Germaine Buck Louis	Dr. Michael Collins (UCLA)